



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EudraVigilance support guide

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Guidance document on the query support options offered by the EMA on EudraVigilance- and Pharmacovigilance-related queries

EMA/434681/2023

29 February 2024

An agency of the European Union





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# Introduction

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# Introduction

The European Medicines Agency (EMA) operates a number of **service desks** to assist Sponsors of Clinical Trials, Marketing Authorisation Holders (MAHs) and National Competent Authorities in using EudraVigilance in the EEA Member States. The working hours are the same as the [EMA's business hours](#).

Enquiries can be submitted through:

## EMA Service Desk Portal

- Web address:  
<https://support.ema.europa.eu/esc>
- Urgent helpline for technical enquiries: +31 (0)88 781 8520

Contact for:

- **Business** questions
- **Technical** questions
- **Application-specific** questions
- Reporting **Duplicates**
- **Medical Literature Monitoring (MLM)**
- **EV QAT Testing**

## EudraVigilance Registration

- Web address:  
[https://support.ema.europa.eu/esc?id=emp\\_taxonomy\\_topic&topic\\_id=5eb1d223c31415508719596ce001312b](https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&topic_id=5eb1d223c31415508719596ce001312b)

Contact for:

- **Registration questions** not found in [EV Registration Manual](#) or webpage  
[EudraVigilance: how to register](#)
- **QPPV/RP change** (or **New Org first user**)
- **Transmission mode change**

## Ask EMA

- Web address:  
<https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency>

Contact for:

- **Pharmacovigilance** or general questions
- **Requests for information**
- To make a formal request for **access to documents**



## EMA Service Desk Portal

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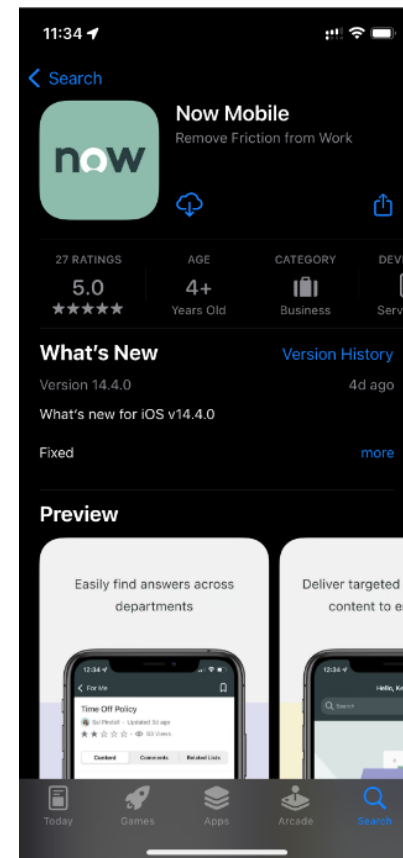
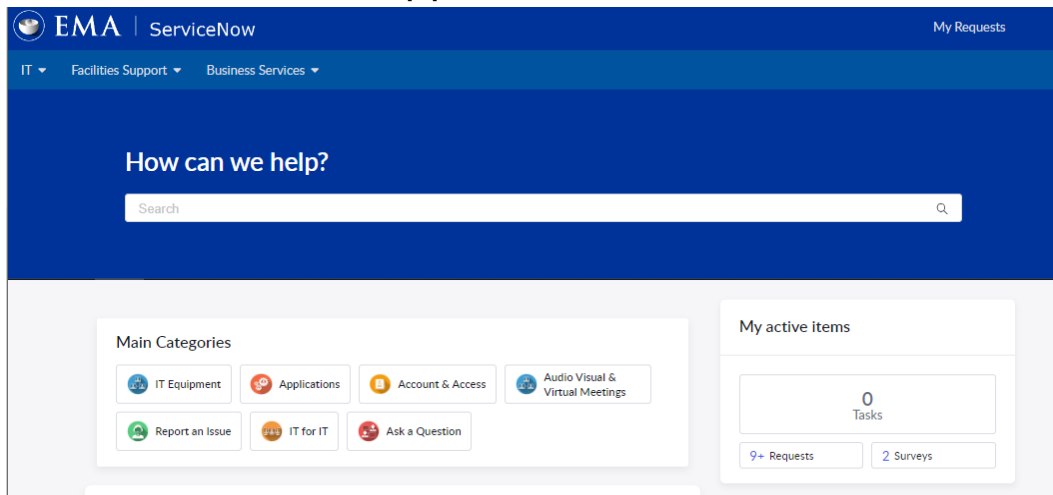
- Update of EMA's Service Desk ticketing system
- Accessing EMA's Service Desk Portal
- Two-factor authentication



# Update of EMA's Service Desk ticketing system

A new, more modern and user-friendly IT platform, ServiceNow, replaced the EMA's old ticketing system (Jira).

This platform went live on 12 September 2022 and is available as a website and has a mobile application.



## Accessing EMA's Service Desk Portal

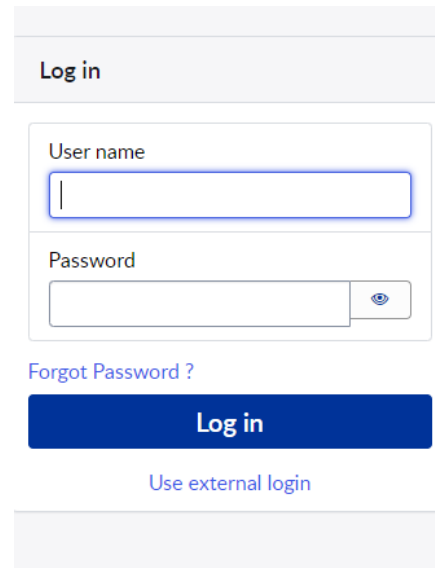
To raise a technical query, request a service related to a specific application or ask a question, use the **EMA's (new) Service Desk Portal**.

The portal can be accessed via this link:

<https://support.ema.europa.eu/esc>

Users already registered with a system hosted by the EMA can use their existing username and password to log in (note that this does **not apply to EudraVigilance accounts**).

Users without EMA login credentials can **create a new EMA Service Desk account** when they first use the portal.



The screenshot shows a login interface with a light grey header containing the text "Log in". Below this is a form with two input fields: "User name" and "Password". The "User name" field is a simple text box. The "Password" field is a text box with a small eye icon to its right, used for toggling password visibility. Below the password field is a blue link that says "Forgot Password?". At the bottom of the form is a prominent blue button with the text "Log in" in white. Below the button is a blue link that says "Use external login". The entire form is set against a light grey background.



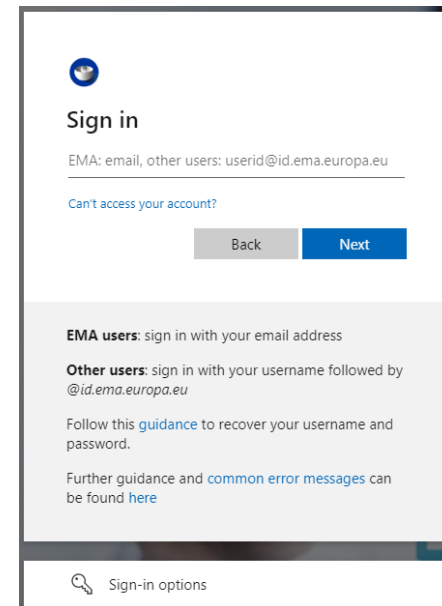
## Accessing EMA's Service Desk Portal: two-factor authentication (2FA)

All EMA 2FA user settings are managed through the following link:

<https://mysignins.microsoft.com/security-info?tenantId=euema.onmicrosoft.com>

Guidance on setting up and managing 2FA for EMA services is described here:

<https://register.ema.europa.eu/identityiq/help/signin.html>







## Accessing EMA's Service Desk via mobile app

To access EMA's Service Desk via the mobile app, please follow these steps:

1. Search for "Now Mobile" in the App-store or the Google Play Store and download the app.
2. When asked for the "Instance Address", enter the following URL: <https://support.ema.europa.eu/>
3. Enter the e-mail address used for regular EMA login.
4. Enter your password.
5. Enter your phone number and select your preferred contact option to verify your identity.
6. Enter the code you have received via call or text message on the phone number provided in the previous step.
7. By clicking on "Stay signed in" you will be able to access to the mobile app faster, by bypassing the login screen.

You have now accessed the Service Desk using the Service Now app.



# Before using the Service Desk Portal

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## Dear User, please note

When raising a ticket with the ServiceDesk, please do **NOT** to include attachments (in any file format including screenshots) that contain:

- special categories of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership as well as genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.
- confidential information including commercially confidential information.

This is with **exception** of confidential information that is required to support of certain business processes e.g., SPOR/XEVMPD and the request for addition/update of substances or standard terms etc.

In case the transmission of attachments is required for other business purposes you are requested, prior submission via the ServiceDesk, to **redact** such information where this is not required for the resolution of your request.



## Dear User, please note

For ServiceDesk requests in relation to **ICSR submissions to EudraVigilance (EV)**, please be advised as follows:

- For individual case(s) already transmitted to EV, please **ONLY** reference the complete E2B(R3) "C.1.1 Sender's (case) safety report unique identifier", the "C.1.8.1 Worldwide unique case identification number" or the EV Local report number (EU-EC-xxxxxxx). EMA can access the cases to resolve your request.
- For safety messages or individual cases that failed a transmission to EV, please only take a **screenshot of the safety Acknowledgment (ACK) Error message** and share such screenshot with the ServiceDesk. In case further information is required, you will be contacted.



## Using the Service Desk Portal

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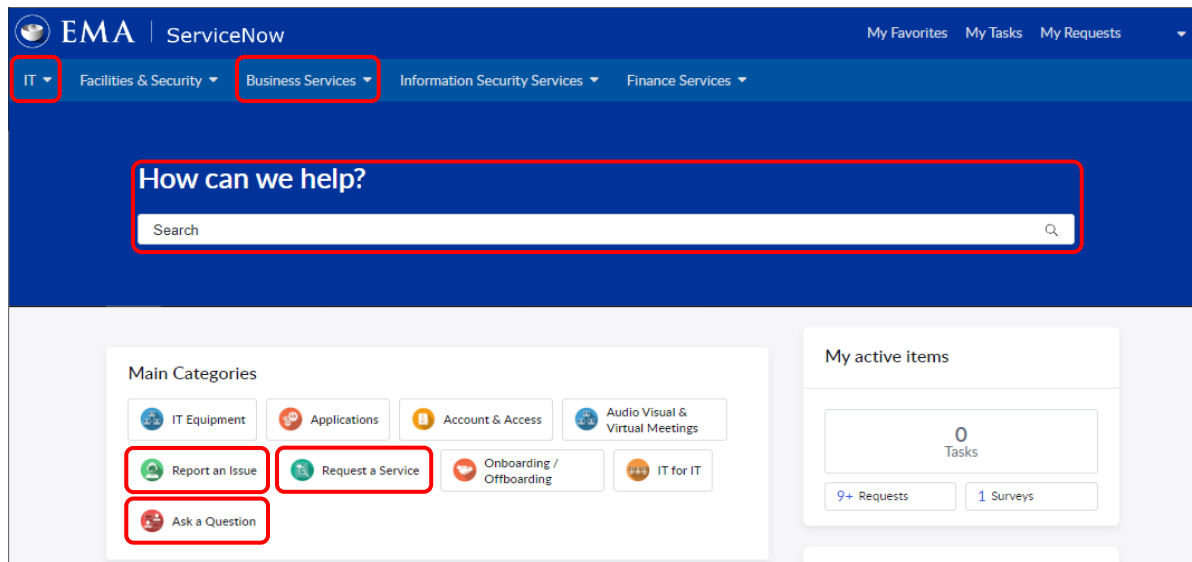
- Ask a Question, Request a Service and Report an Issue related to EV
- Raise Medical Literature Monitoring (MLM) related queries
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- Raise EudraVigilance Registration-related queries
- Track enquiries in EMA's Service Desk

## Using the Service Desk portal

Use the right category to log the calls related to EudraVigilance or other EMA supported IT systems such as EudraLink.

For some services (e.g. **MLM**, **ICSR duplicates** or **EV QAT**) there are *specific* forms that should be used instead.

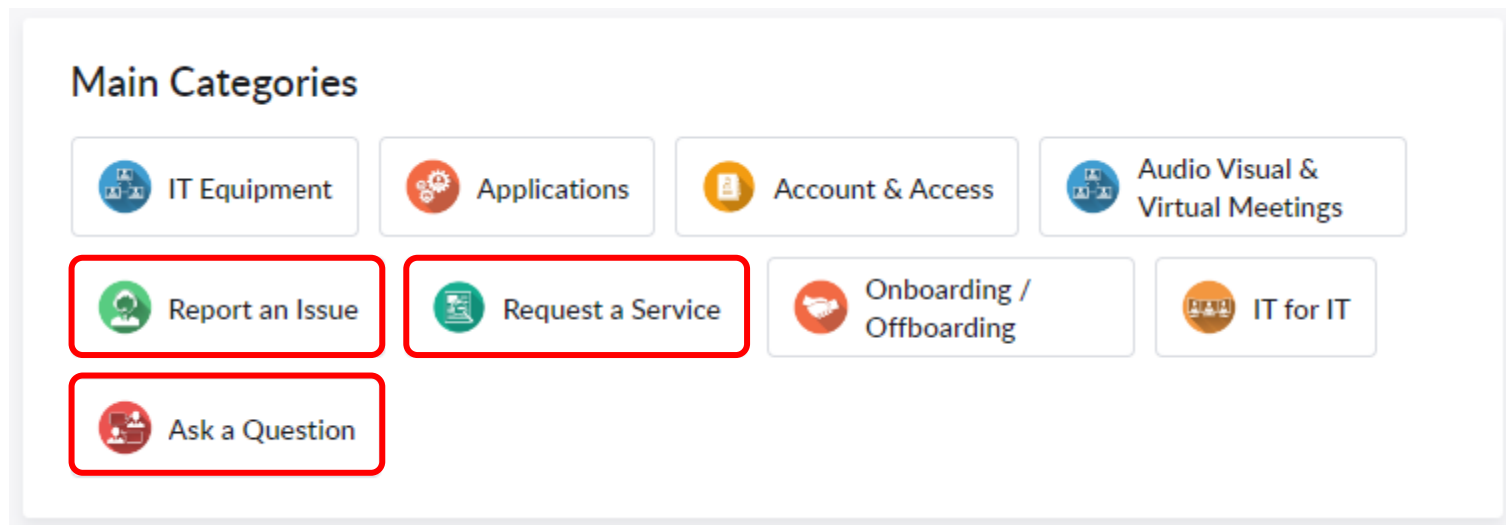
These forms can be found under “IT” or “Business Services” (or when searching for them in the Search bar).





## Using the Service Desk portal

In the Main Categories, you can **Ask a Question**, **Request a Service** or **Report an Issue**:





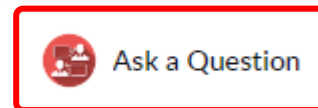
# Using the Service Desk portal

## Ask a Question:

If you have **general** or **technical** (related to the use of EMA's IT systems) **questions**, or if you have questions or any other inquiries not falling under the "Request a Service" or "Report an Issue" sections.

Some examples:

- if you don't know how to use a system or **cannot upload a file**;
- if you've made a **mistake** when using a system (such as **EVWEB**);
- if you cannot retrieve an **ICSR** in EV or have a query related to that case;
- if you've received a **Negative acknowledgment (ACK)**.





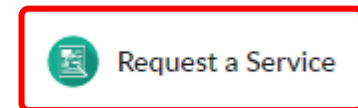
# Using the Service Desk portal

## Request a Service:

If you need to help with **access, passwords, unlocking accounts** for the EudraVigilance systems or need to **raise specific requests**.

Some examples:

- If you need to request **Gateway** or **Eudralink** access;
- If you need a service related to **EV Registration, Art.57/XEVMPD** or **SPOR**.





## Using the Service Desk portal

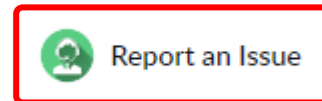
### Report an Issue:

If an EudraVigilance-related **system is unavailable OR is malfunctioning** (i.e., needs **fixing**).

For example: EVWEB, EVDAS or EudraLink is unavailable.

### Note:

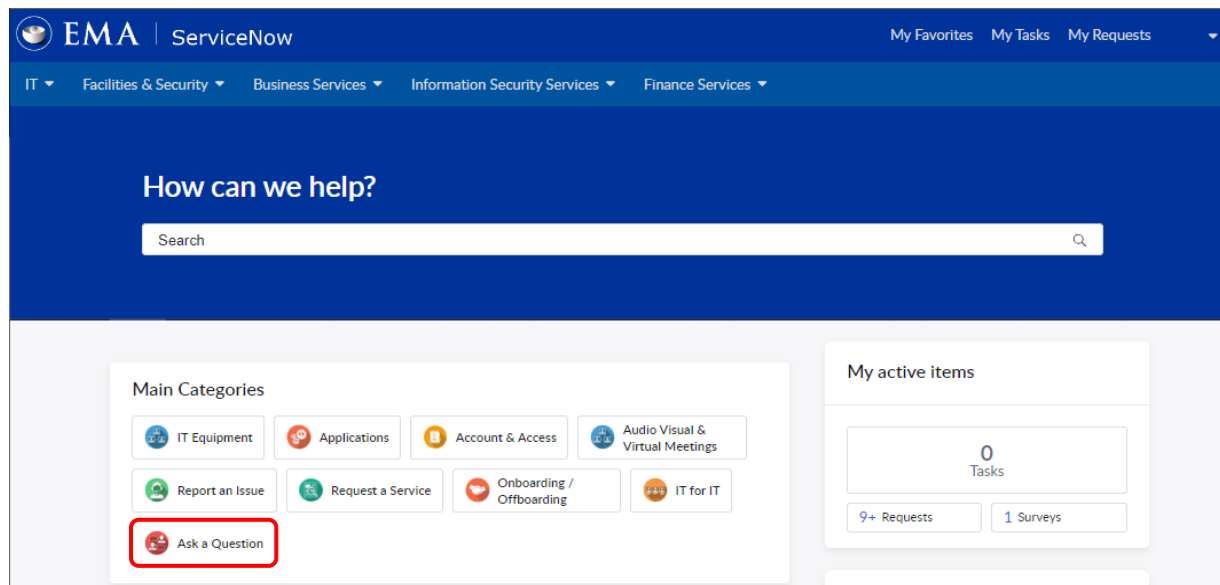
**Errors/mistakes** made by users, for example when submitting a case in EVWEB, are **NOT** Issues and should be reported **only** via **“Ask a Question”**.



# Using the Service Desk to **Ask a Question**

In the “Main Categories”,  
click on “**Ask a Question**”.

Please note the option “**Ask a Question**” should be used for asking **general** or **technical questions**.



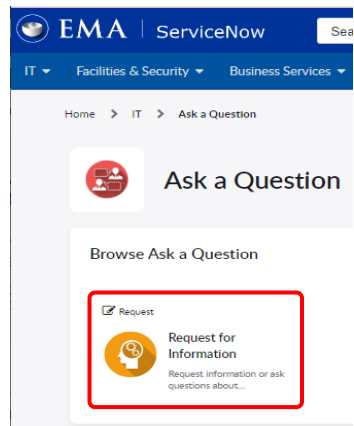
# Using the Service Desk to Ask a Question

Click on “Request for Information” and complete the form.

You should select the relevant Service, for example “EudraVigilance”, and then select the intended Service Offering, such as “EVWEB ICSR” or “EVDAS”.

All the fields marked with a star \* at the beginning are mandatory.

An option for attaching a file is also available.




**Request for Information** ♥

Request information or ask questions about Information Management

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Use this service to request information.



- \* Indicate required information
- \* Raise this request on behalf of  x ▾
- \* Subject
- \* Service
- \* Service Offering
- \* Description

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

- Special categories of personal data
- Confidential information

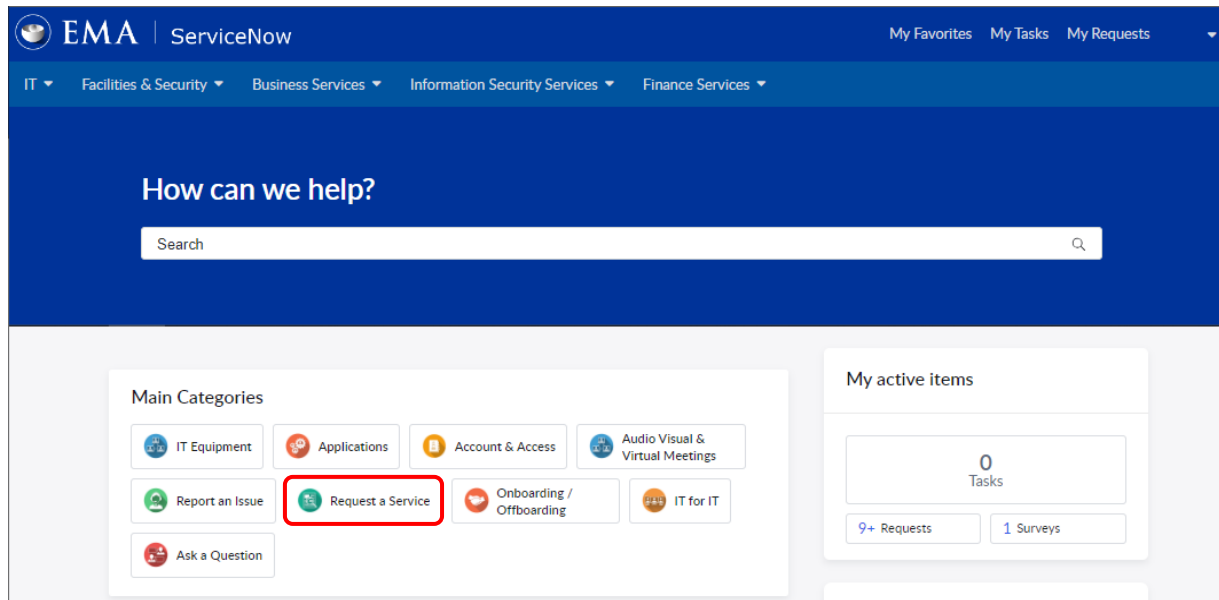
Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use

# Using the Service Desk to **Request a Service**

In the “Main Categories”, click on “**Request a Service**”.

Please note the option “**Request a Service**” should be used for issues with **access / passwords, unlocking accounts** for the EudraVigilance systems or need to **raise specific requests**.



The screenshot shows the EMA ServiceNow portal. At the top, there is a navigation bar with the EMA logo and 'ServiceNow' text. Below this, there are several menu items: IT, Facilities & Security, Business Services, Information Security Services, and Finance Services. The main content area features a search bar and a 'How can we help?' heading. Below the search bar, there is a 'Main Categories' section with several buttons: IT Equipment, Applications, Account & Access, Audio Visual & Virtual Meetings, Report an Issue, **Request a Service** (highlighted with a red box), Onboarding / Offboarding, and IT for IT. To the right of the 'Main Categories' section, there is a 'My active items' section showing 0 Tasks, 9+ Requests, and 1 Surveys.



# Using the Service Desk to Request a Service

Select the Service related to the issue you wish to report a problem (for example: "Request Eudralink Account").

Please note you can expand the options currently displayed by clicking on "Show more".

The screenshot shows the EMA ServiceNow portal interface. At the top, there is a navigation bar with the EMA logo, 'ServiceNow' text, a search bar, and user options like 'My Favorites', 'My Tasks', and 'My Requests'. Below this is a breadcrumb trail: 'Home > IT > Request a Service'. The main content area is titled 'Request a Service' and features a 'Browse Request a Service' section. This section includes a filter dropdown set to 'Request' and a sort dropdown set to 'Popular'. A grid of 12 service request cards is displayed, each with an icon, a title, and a brief description. The cards include: 'ACS - Oracle Non-Standard Request', 'Request Eudralink Account', 'Access to Any other Application', 'EudraVigilance Registration queries', 'Request SMS services', 'Request XEVMPD/Art.57...', 'Request Gateway Access', 'Request Support for a Future Meeting', 'Request Webex Meeting Support', 'IM - Network Monitoring Security', 'Account Unlock', and 'Request OMS services'. A red rectangular box highlights the 'Show more' button located at the bottom right of the grid.

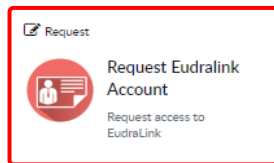
# Using the Service Desk to **Request a Service**

Once you've selected the Service, you should complete the corresponding form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu or complete the field with free text in order to submit your call.

An option for attaching a file is also available.




### Request Eudralink Account ♥

Request access to EudraLink

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Use this service to request changes in permission settings for EudraLink.



\* Indicate required information

\* Raise this request on behalf of

👤 ✕ ▾

\* Motivation ⓘ

Please indicate what you intend to use your Eudralink account for. This should relate to pharmaceutical regulatory purposes or communications that are relevant to EMA. ✕

\* Summary

\* Confirmation

I confirm my understanding of the Eudralink policy

- I am aware that the Eudralink user account is strictly personal, and I certify that I will not permit any other person to use my account.
- I will not disclose my account password to any third party.
- I am aware that the Eudralink service could be suspended for maintenance purposes or network failures.
- I certify that I will use Eudralink services for Pharmaceutical Regulatory purposes only or communications that are relevant to EMA.



# Using the Service Desk to Report an Issue

In the “Main Categories”, click on “**Report an Issue**”.

Please note the option “**Report an Issue**” should be used **ONLY** for **reporting issues** related to the **unavailability** of an EMA system (such as EVWEB or EudraLink) OR if the IT system is **malfunctioning** (i.e., needs fixing).

Hence, queries related to, for example, **errors/mistakes** the user has made upon submitting an ICSR to EV should **NOT** be raised as an Incident but, instead, via “**Ask a Question**”.

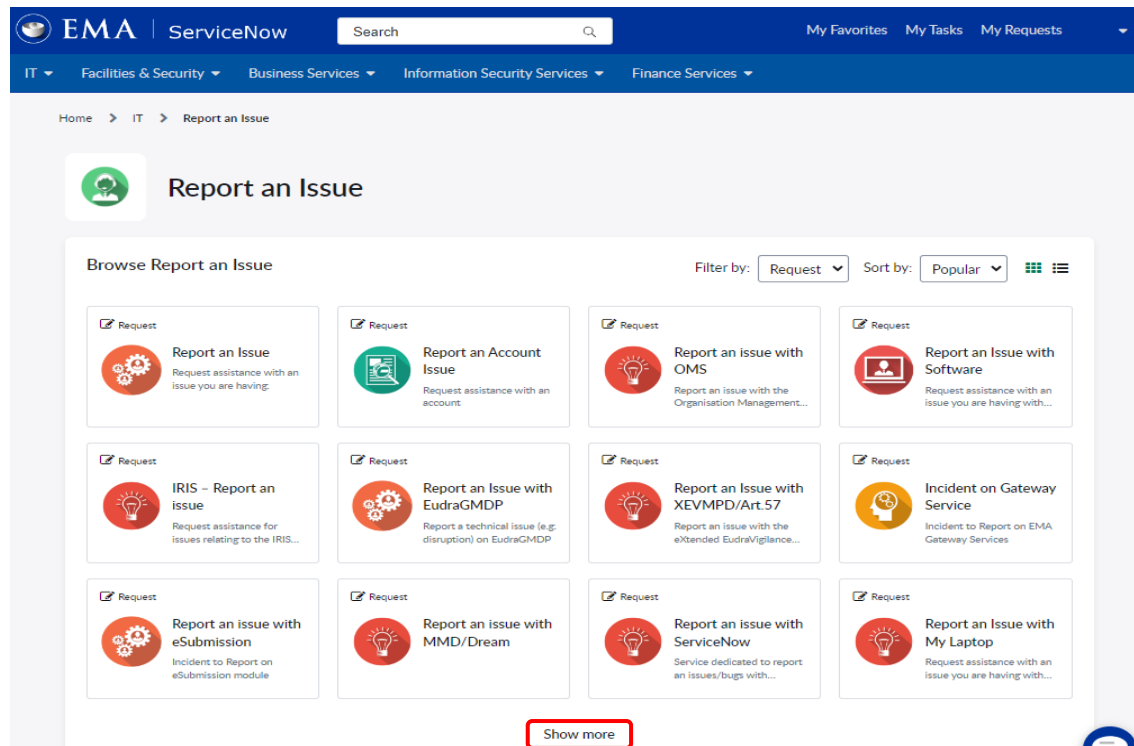
The screenshot displays the EMA ServiceNow portal interface. At the top, the header includes the EMA logo, the text 'EMA | ServiceNow', and navigation links for 'My Favorites', 'My Tasks', and 'My Requests'. Below the header, there are dropdown menus for 'IT', 'Facilities Support', 'Business Services', and 'Information Security Services'. The main content area features a search bar with the text 'How can we help?' and a search input field. Below the search bar, the 'Main Categories' section is visible, containing several service tiles: 'IT Equipment', 'Applications', 'Account & Access', 'Audio Visual & Virtual Meetings', 'Request a Service', 'Onboarding / Offboarding', 'IT for IT', and 'Ask a Question'. The 'Report an Issue' tile is highlighted with a red border. To the right of the 'Main Categories' section, there is a 'My active items' section showing '0 Tasks', '9+ Requests', and '4 Surveys'.



# Using the Service Desk to Report an Issue

Select the Service related to the issue you wish to report a problem (for example: "Report an Issue with XEVMPD/Art.57").

Please note you can expand the options currently displayed by clicking on "Show more".



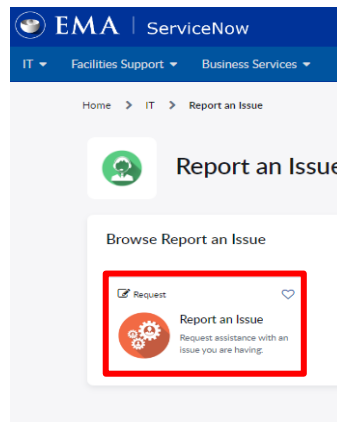
# Using the Service Desk to Report an Issue

Click on the Service (for example: "Report an Issue") and complete the form.

You should select the relevant **Service**, for example "EudraVigilance", and then select the intended **Service Offering**, such as "EVWEB ICSR" or "EVDAS".

All the fields marked with a star \* at the beginning are mandatory.

An option for attaching a file is also available.



### Report an Issue

Request assistance with an issue you are having.

Report an issue you are having regarding IT systems, applications or devices, by filling out the following form. Make sure to include as much detail as possible. An incident record will be created and managed through to successful resolution. You will also be notified of progress.

**Examples:**

- Report an issue with business applications / software / network connectivity
- Issues with audio visual meeting room equipment (e.g. projectors, voting system or audio quality)

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**\* Indicate required information**

**\* Raise this request on behalf of**

**\* Service**

**\* Service Offering**

**\* Subject**

**\* Description**

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use



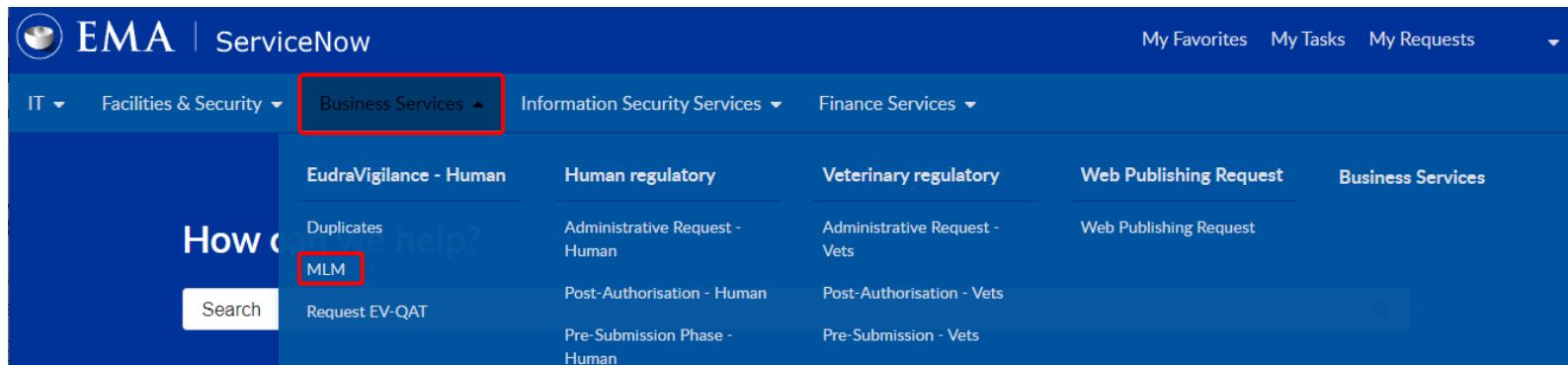
# EudraVigilance – MLM queries

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# Raise Medical Literature Monitoring (MLM)-related queries

General guidance on the EMA's MLM Service is detailed in the webpage [Medical literature monitoring](#) and in the document [Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency – Questions and Answers](#).

To raise a query related to the MLM Service, go to “Business Services” and click on “MLM”.



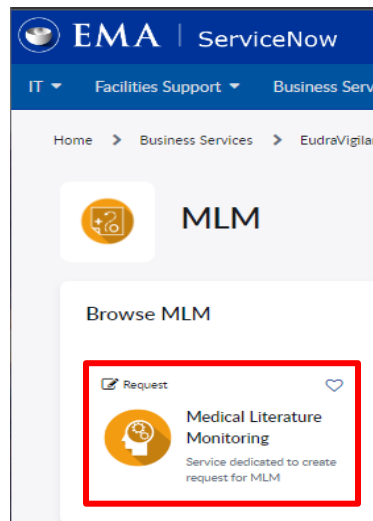
# Raise Medical Literature Monitoring (MLM) related queries

Click on “Medical Literature Monitoring” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.


You will have to choose a value from the drop-down menu or complete the field with free text in order to submit your call.

An option for attaching a file is also available.



### Medical Literature Monitoring

Service dedicated to create request for MLM



This form is for reporting any questions or issues you have found regarding the data originating from the MLM Service. If you have identified a bug in the EVWEB regarding the MLM software, please use the EV Service Desk.

\* Indicate required information

\* Raise this request on behalf of

\* Subject

\* Description

\* Type of enquiry

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

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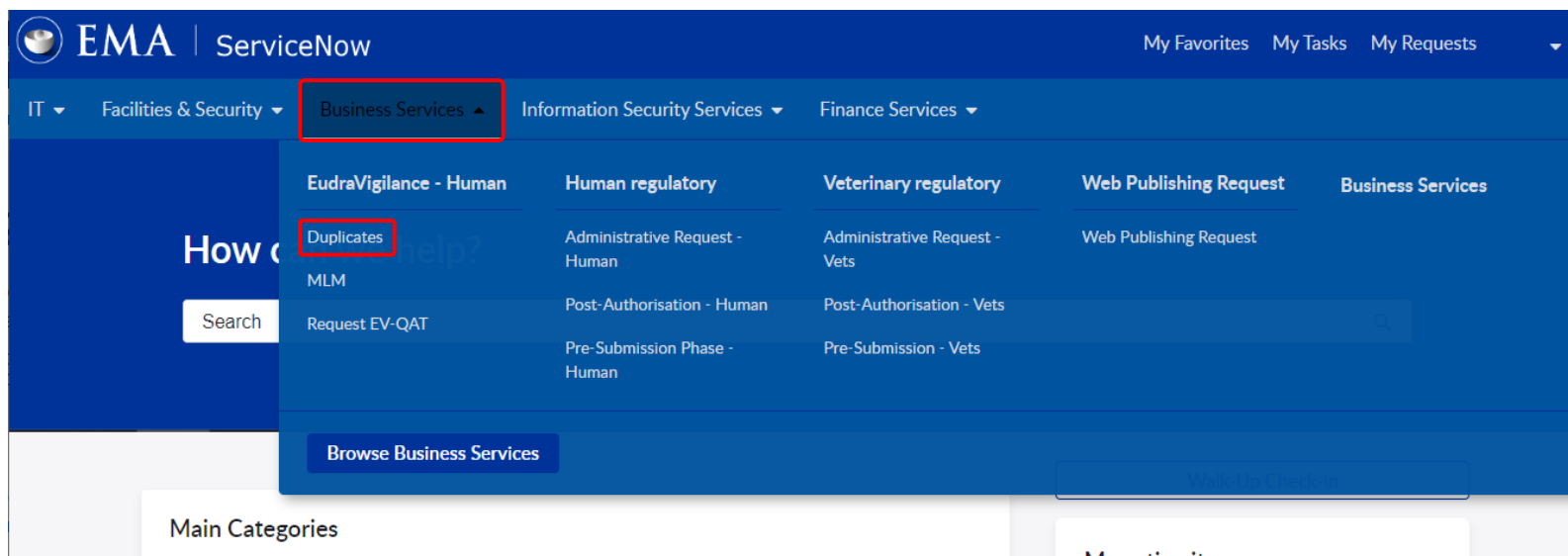


# EudraVigilance – Report ICSR Duplicates

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# EudraVigilance – Report ICSR Duplicates

To report ICSR duplicates in EV, go to “Business Services” and click on “Duplicates”.



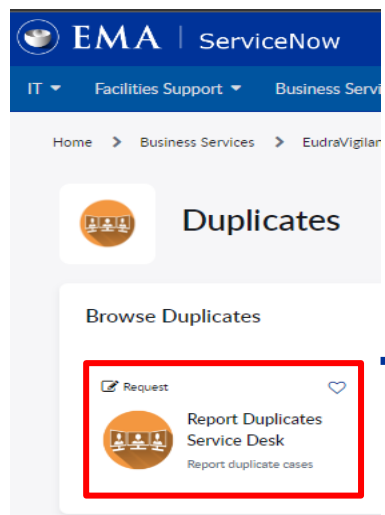
# EudraVigilance – Report ICSR Duplicates

Click on “Report Duplicates Service desk” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.


You will have to choose a value from the drop-down menu or complete the field with free text in order to submit your call.

An option for attaching a file is also available.



### Report Duplicates Service Desk

Report duplicate cases



Use this form to report suspected duplicate cases you have found in EudraVigilance.

Please enter case numbers or safety report IDs in full E2B format or local report numbers.

Please only enter the identification numbers of cases you have found in, or submitted to, EudraVigilance. If you have found an identification number in the 'Other case identifiers' section of a case, you do not need to report this.

Please do not attach any individual cases. We will be able to access them in EV with the identifiers.

If you are attaching a line listing of cases, please indicate which cases you suspect of being duplicates.

\* Indicate required information

\* Raise this request on behalf of

\* Description

\* Choose one of the below types of Reference Numbers

Please click in the text box and choose a reference number you are providing for the reported duplicate. \*

\* Number of cases to be reported

Note

If you have more than 15 suspected duplicates, please attach the spreadsheet in the requested format. \*

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use





# EudraVigilance – Request EV QAT

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## EudraVigilance – Request EV QAT

Please note that EudraVigilance Quality Assurance Testing (QAT) needs to be completed with EMA whenever an organisation wants to, for example:

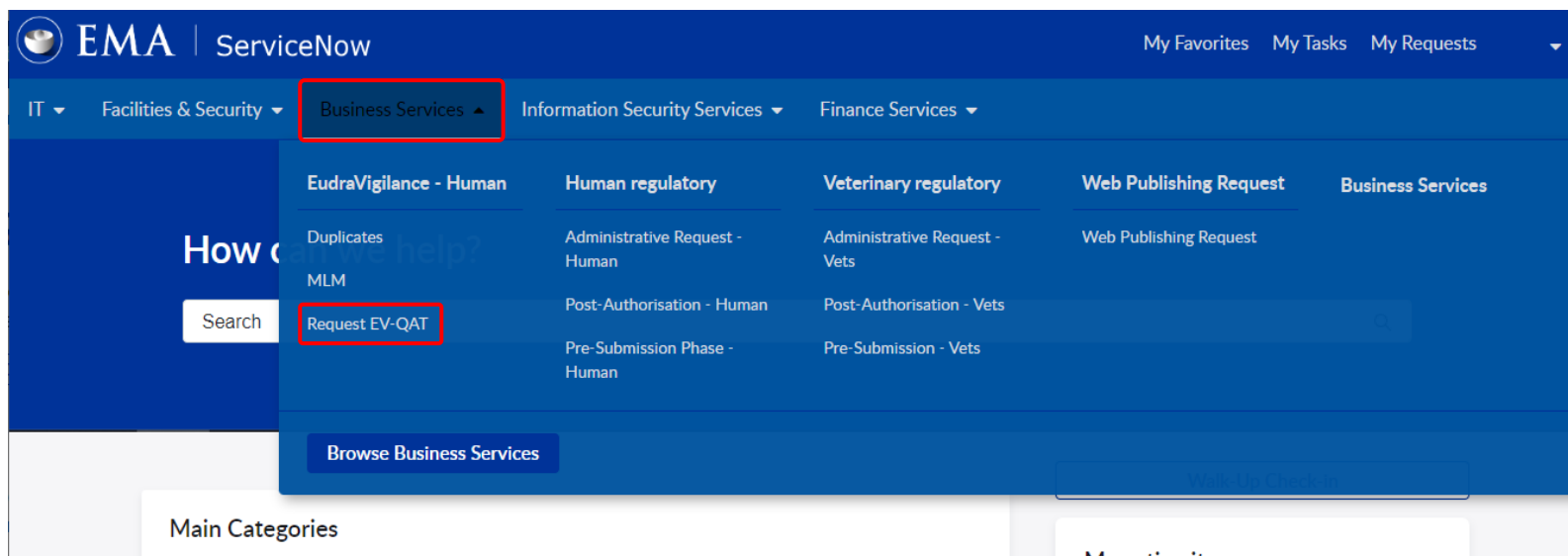
- Have the **EV transmission mode changed from WebTrader to Gateway Trader**;
- Start using **EVPOST** (for organisations using EVWEB); or
- Upgrade their **PV database** (for organisations operating as Gateway Traders or using EVPOST).

This is further detailed on EMA's webpage [EudraVigilance: electronic reporting](#). Please also refer to [EV Registration Manual](#) (namely to section 6.1).

Before initiating QAT (also known as Step 5 testing) with EMA, **all organisations are required to complete Step 4 testing themselves in advance**. Only then should Step 5 testing begin. Guidance on how to complete these 2 testing steps is available on the EMA's webpage linked above.

# EudraVigilance – Request EV QAT

To request EV QAT, go to “Business Services” and click on “Request EV-QAT”.



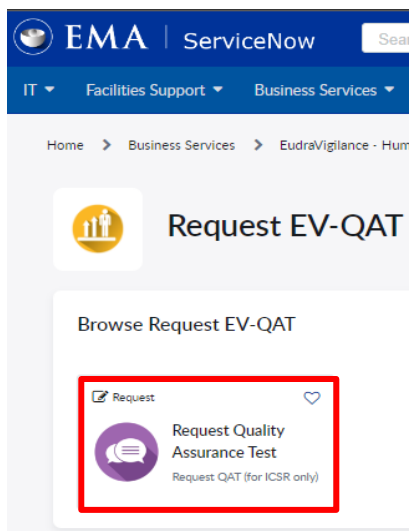
# EudraVigilance – Request EV QAT

Click on “**Request Quality Assurance Test**” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.

You will have to choose a value from the drop-down menu or complete the field with free text in order to submit your call.

An option for attaching a file is also available.



The form is titled 'Request Quality Assurance Test' and is for ICSR only. It contains several mandatory fields marked with a star (\*):

- \* Indicate required information
- \* Raise this request on behalf of (dropdown menu)
- \* Subject (text field)
- \* Description (text field)
- \* XCOMP Organisation Sender Identifier (this EV Sender identifier has the format "ORXnnnnnnnn" or "VXnnnnnnnn") (text field)
- \* Organisation Name (text field)
- \* Are you using a Gateway or the EVPOST function? (dropdown menu)
- \* Please confirm that you've completed Step-4 testing prior to submitting this QAT request, as explained at the top of this form (if you need support to complete Step 4 testing, then please mention it in the "Description" field of this form). (dropdown menu)
- \* Are you a Software Vendor, a CRO/Service Provider or MAH/Sponsor/NCA? (dropdown menu)
- \* Name of the PV software (text field)
- \* Version of the PV software (text field)
- \* Configurations of the PV software (text field)



# EudraVigilance Registration

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## EudraVigilance Registration Queries & Requests

Please note that the EMA EV registration team only deals with queries for the following EV Human production topics:

- **New Organisation;**
- **QPPV/RP change** or **first user activation;**
- **Change in transmission mode.**

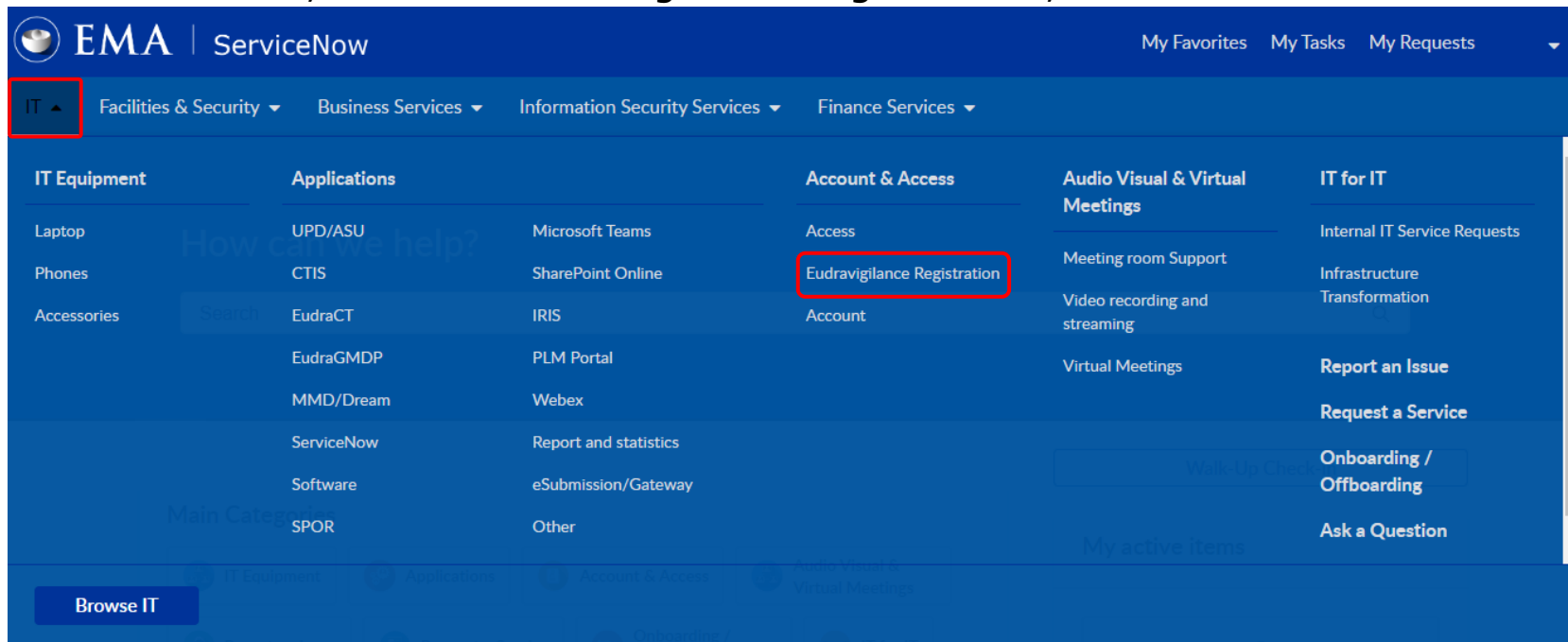
For more information, please refer to the webpage [EudraVigilance: how to register](#) and to the documents [EV Registration manual](#), [EudraVigilance registration documents](#) and [New Organization First User QPPV/RP or Change of EU QPPV/RP](#).

Other EudraVigilance-related queries should be sent as EMA Service Desk requests:

- **Ask a Question;**
- **Request a Service;**
- **Report an Issue.**

# EudraVigilance Registration Queries & Requests

In the "IT" section, click on "EudraVigilance Registration", under "Account & Access".



The screenshot shows the EMA ServiceNow interface. At the top, there is a navigation bar with the EMA logo and 'ServiceNow' text. To the right of the logo, there are links for 'My Favorites', 'My Tasks', and 'My Requests'. Below this is a main navigation menu with several categories: 'IT', 'Facilities & Security', 'Business Services', 'Information Security Services', and 'Finance Services'. The 'IT' category is expanded, showing a grid of sub-categories: 'IT Equipment', 'Applications', 'Account & Access', 'Audio Visual & Virtual Meetings', and 'IT for IT'. Under the 'Account & Access' category, the 'EudraVigilance Registration' link is highlighted with a red box. Other links in this category include 'Access' and 'Account'. At the bottom of the page, there is a 'Browse IT' button and a row of quick links: 'Report an Issue', 'Request a Service', 'Onboarding / Offboarding', and 'IT for IT'.

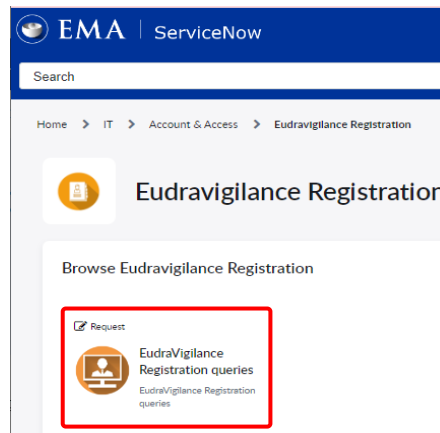
# EudraVigilance Registration Queries & Requests

Click on “**EudraVigilance Registration queries**” and complete the form.

All the fields marked with a star \* at the beginning are mandatory.


You will have to choose a value from the drop-down menu or complete the field with free text in order to submit your call.

An option for attaching a file is also available.



### EudraVigilance Registration queries

EudraVigilance Registration queries



- For new access or password reset please go to [EMA Account Management](#).
- For user password reset or unlocking your account, please go to the [Account Unlock - Employee Center \(europa.eu\)](#).
- To create new organizations or manage an existing one, please log into [SPOR Organization Management System](#).
- For QPPV/RP changes please check our [Registration Manual](#).

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\* Indicate required information

\* Raise this request on behalf of

\* Subject

\* Description

\* EV-Environment type

EV-Request type

Registering/Changing MAH QPPV/RP

EU QPPV

Responsible Person

Amending my organization profile

Registering/Disabling an org/user

Other

Dear ServiceDesk User,

When raising a ticket with the ServiceDesk, we advise you not to include attachments that contain:

- Special categories of personal data
- Confidential information

Please read the [Terms of use](#).

In order to add an attachment please indicate that you agree to the Terms of Use





## EMA Service Desk – Tracking enquiries

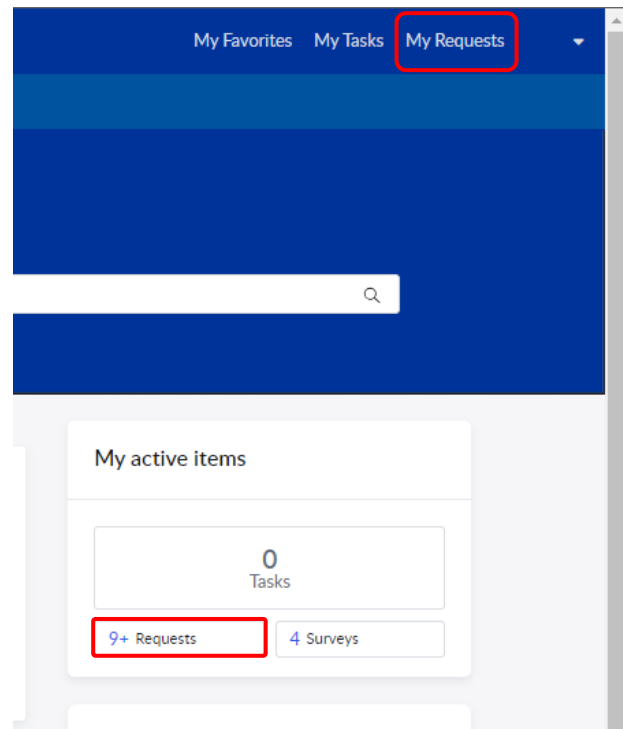
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## EMA Service Desk – tracking enquiries

Once you have submitted an enquiry, you will receive an email notification with a **reference number** of your enquiry (to the email address you've provided upon registering).

An overview of all your raised queries can be viewed by clicking on the “**Requests**” button, under “My active items”, or on the “**My Requests**” button at the top of any EMA Service Desk page.

When your enquiry has been updated, you will receive an **email notification** containing a **link to the enquiry update**.

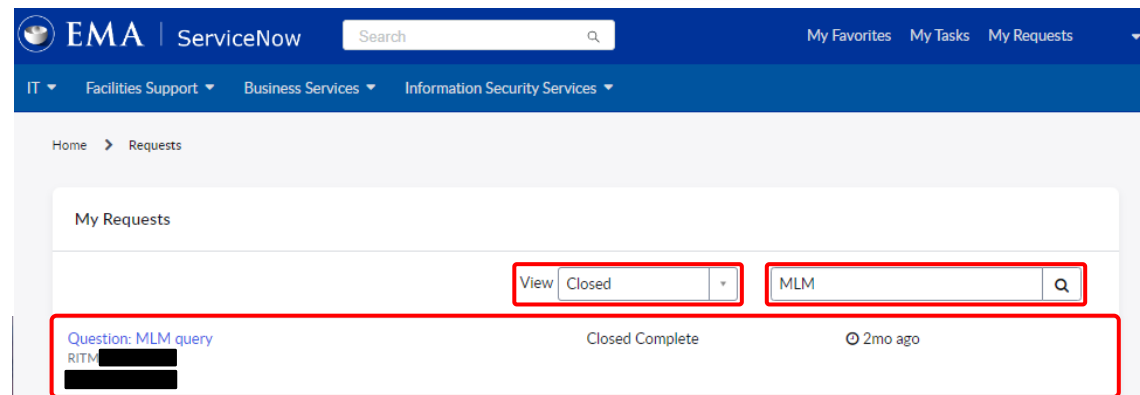
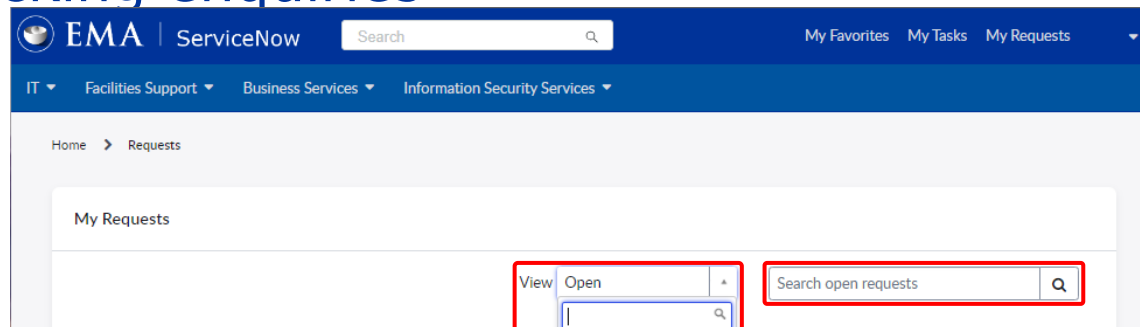




## EMA Service Desk – tracking enquiries

If you are searching for a particular logged query, type the **reference number** or the **topic/subject** of your query in the “**Search open requests**” search bar to view the results retrieved.

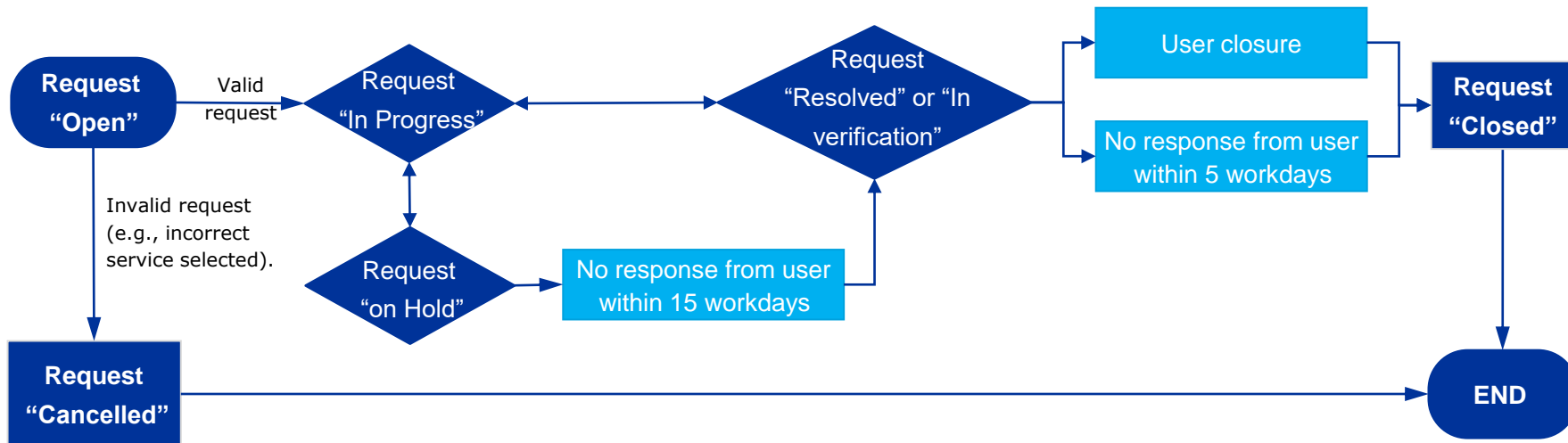
You have the option to filter the request you want to view in the “**View**” section. For example, “Closed Request” for “MLM”.



## EMA Service Desk – Resolving enquiries

Resolved enquiries will be have the status “**Resolved**” or “**In verification**”.

If further clarification is needed, your enquiry can be re-opened within five workdays of the ticket being resolved.





## EMA Service Desk – Resolving enquiries

Users can manually close the query via the detailed query page in the “My Requests” section. Queries will be automatically closed within five workdays.

The screenshot displays the EMA ServiceNow interface. At the top, there is a navigation bar with the EMA logo, 'ServiceNow', a search bar, and links for 'My Favorites', 'My Tasks', and 'My Requests'. Below this is a secondary navigation bar with categories like 'IT', 'Facilities Support', 'Business Services', and 'Information Security Services'. The main content area shows a breadcrumb trail 'Home > My Request - RITM [redacted]'. A table lists request details with columns for 'Number', 'Created', 'Updated', and 'State'. The 'Number' column shows 'RITM [redacted]', 'Created' shows '5mo ago', 'Updated' shows '6d ago', and 'State' shows 'Verification'. Below the table, the 'Question:' field contains a redacted text. To the right of the question, there are two buttons: a red 'Reopen' button and a green 'Confirm Close' button. Further down, the 'Name' field is redacted, and the 'Opened' date is '5mo ago'. The 'Stage' is set to 'Verification'.



## Ask EMA

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- General- or Pharmacovigilance-related questions
- Requests for information
- Formal request for access to documents



## Ask EMA

To raise a **general query**, ask EMA a specific question about a **pharmacovigilance-related issue**, **requests for information** or to make a **formal request for access to documents** that are not already published on Agency's website, use the web form available under the link:

<https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency>

**Home > About us > Contacts > Send a question to the European Medicines Agency**

No registration is necessary.



# Ask EMA

## Your question

Your name

Organisation/Employer

If you are not representing a particular organisation please write 'Not applicable' into this field.

Who are you?

Location

Please select your type of enquiry

- I want you to answer a question
- I want an unpublished document (maximum 2 documents per request)
- I want help identifying which unpublished document I need

For more information on these enquiry types and how we handle them, see:

- [The European Medicines Agency code of good administrative behaviour](#)
- [Access to documents](#)
- [Guide on access to unpublished documents](#)



Enter your **personal** and **organisation's details** in this section.





# Ask EMA

What is the subject of your enquiry?

For example "Question on", "Request for"

Your question(s)

Please type your clear question or request here.

Please type your clear question or request here. Where possible please provide a link, a product name, a reference number or the name of the document or topic you are interested in. Please do not include any personal data, such as your name or contact details in this field.

Your email address

Enter your email address

We will only use your email address to contact you about your query.

Please retype your email address

Confirm your email address

I have read and agree with the data protection terms [Data protection and privacy](#).

Send question

← Enter the **details of your enquiry** in this section

← Enter your **contact details** in this section so that the Agency can get back to you.



## Additional sources of information

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# Additional sources of information

## EV:

- [EudraVigilance system overview](#)
- [EudraVigilance: electronic reporting](#)
  - [What to do in case of system failure](#)
- [The launch of the new EudraVigilance System – Questions and answers \(Q&A\) from stakeholders](#)
- [ICH E2B \(R3\) Guideline](#)
- [EU Individual Case Safety Report \(ICSR\) Implementation Guide](#)
- [EudraVigilance - EVWEB User Manual](#)
- [Change management for the EudraVigilance system](#)
- [EudraVigilance training and support](#)

## EV Registration:

- [EudraVigilance: how to register](#)
- [EMA EudraVigilance Registration Manual](#)
- [EudraVigilance registration documents](#)

- [New Organization First User QPPV/RP or Change of EU QPPV/RP](#)

## SUSARs:

- [Reporting safety information on clinical trials](#)

## ICSRs:

- [GVP Module VI](#)
- [GVP Module VI – Addendum I](#)
- [CHMP Guideline on detection and management of duplicate individual cases and Individual Case Safety Reports \(ICSRs\)](#)

## MLM:

- [Medical literature monitoring](#)
- [Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Questions and Answers](#)



# Contact Points Summary

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# Contact Points Summary

Contact point	Areas	Contact
<b>EMA Service Desk Portal</b>	<ul style="list-style-type: none"> <li>• EudraVigilance</li> <li>• Technical- or application-specific queries</li> <li>• MLM</li> <li>• Duplicates</li> <li>• EV QAT</li> </ul>	<b>EMA Service Desk portal:</b> <a href="https://support.ema.europa.eu/esc">https://support.ema.europa.eu/esc</a>
<b>EudraVigilance Registration Team</b>	<ul style="list-style-type: none"> <li>• EV Registration-related issues</li> </ul>	<b>EudraVigilance Registration Queries:</b> <a href="https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&amp;topic_id=5eb1d223c31415508719596ce001312b">https://support.ema.europa.eu/esc?id=emp_taxonomy_topic&amp;topic_id=5eb1d223c31415508719596ce001312b</a>
<b>Ask EMA</b>	<ul style="list-style-type: none"> <li>• Pharmacovigilance-related enquiries</li> <li>• General Queries</li> <li>• Access to documents</li> </ul>	<b>Ask EMA:</b> <a href="https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency">https://www.ema.europa.eu/en/about-us/contacts-european-medicines-agency/send-question-european-medicines-agency</a>
<b>Urgent Technical Helpline</b>	<ul style="list-style-type: none"> <li>• Urgent technical or application-specific queries</li> </ul>	<b>Urgent technical helpline:</b> +31 (0)88 781 8520



## Further information

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If urgent assistance is needed with EMA's IT systems, please phone **+31 (0)88 781 8520**

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Telephone** +31 (0)88 781 6000

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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